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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/725,182	11/29/00	RYAN	0207-0007 (W)

HM22/0411

OFFICE OF THE STAFF JUDGE ADVOCATE  
U.S. ARMY MEDICAL RESEARCH AND MATERIEL  
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)  
504 SCOTT STREET  
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EXAMINER  
SHAHNAN-SHAH, K

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/11/01 *S*

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/725,182	RYAN ET AL.
	Examiner Khatol S Shahnan-Shah	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims 1-40 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:

1. received.

2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.

3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

19) Notice of Informal Patent Application (PTO-152)

20) Other: \_\_\_\_\_

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, 27 and 29 are, drawn to an immunoassay method and a kit for detection of an antibody in a sample, classified in class 435, subclass 7.2.
- II. Claims 21-26, 28 and 30 are, drawn to a kit for detecting an antigen in a sample, classified in class 242, subclass 184.1.
- III. Claim 31 is, drawn to a method preparing an antibody classified in class 530, subclass 387.1.
- IV. Claim 32 is, drawn to a method preparing an antigen classified in class 436, subclass 500.
- V. Claim 33 is, drawn to a method detecting a parasite, classified in class 435, subclass 7.22.
- VI. Claims 34-36 are, drawn to a protein free culture medium, classified in class 435, subclass 258.3.
- VII. Claims 37-40 are, drawn to a method obtaining an antigen from a parasite using protein free medium, classified in class 530, subclass 403.

2. The inventions are distinct, each from the other because of the following reasons:  
Groups I, III, IV, V, and VII are drawn to different methods. The claims of group I are drawn to a an immunoassay method and a kit, that of group III is drawn to a method preparing an antibody, that of group IV is drawn to a method preparing an antigen, that of group V is drawn to a method detecting a parasite, those of group VI I are drawn to a method obtaining an antigen.

The inventions are shown to be distinct because they are drawn to distinct methods, which differ in method objectives, method steps, reagents and material used.

Groups II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antigen used in the kit can be produced by harvesting tissue cultures of the parasites.

Groups II and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antigen can be obtained from tissue cultures, using protein-containing media.

Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antigen prepared can be used to do a skin test for diagnosis of the parasite.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Conclusion*

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Khatol Shahnan-Shah* 3/29/01  
Khatol Shahnan-Shah, BS, Pharm, MS  
Biotechnology Patent Examiner

*Rodney P. Swartz*  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER  
3/29/01